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EXAMINER
EINSMANN, JULIET CAROLINE

ART UNIT	PAPER NUMBER
1634	15

DATE MAILED: 06/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/627,465	Applicant(s) KEITH, TIM	
	Examiner Juliet Einsmann	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-19,22-26 and 28-74* is/are pending in the application.

4a) Of the above claim(s) *16-19,22-26 and 28-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *34-74* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *13* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, SEQ ID NO: 1 in Paper No. 10 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Upon further consideration of the elected claims, the examiner decided that a partial rejoinder of the sequences was appropriate. The nucleic acid of SEQ ID NO: 1 is the insert from a genomic BAC (bacterial artificial chromosome). The particular nucleic acids of SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 6, SEQ ID NO: 8, and SEQ ID NO: 10 are alternately spliced cDNAs from this sequence. In accordance with common practice, the genomic sequence is being rejoined to the cDNA sequences. Thus, there are five separate groups within elected group I, wherein each group contains one of the cDNAs and the genomic SEQ ID NO: 1. The genomic SEQ ID NO: 1 will be examined with whichever cDNA is elected.

3. Applicant elected SEQ ID NO: 2, the nucleic acid encoding SEQ ID NO: 3 for examination along with SEQ ID NO: 1 in a telephonic interview on May 22, 2002. Because all claims to this subject matter had been previously cancelled, new claims 56-74 were added by amendment (paper number 11).

Claim Objections

4. Claims 52, 53, and 74 are objected to because of the following informalities: The claims contain references to sequence and SNP sites described in tables.

> MPEP 2173(s) states "Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table is permitted only in exceptional

> circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience."

In the instant case it would be possible to refer to the claimed sequences and SNP sites using proper sequence identifiers and phraseology. Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 34-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 34-41 are indefinite over the recitation "a complementary nucleic acid sequence of SEQ ID NO: 1" in independent claim 34 because it is not clear if applicant is claiming the sequence that is complementary to SEQ ID NO: 1 over its entire length or over some portion of SEQ ID NO: 1. Recitation of "the complement of SEQ ID NO: 1" would obviate this rejection.

Claims 34-41 are indefinite over the recitation "under stringent conditions" because it is not clear how this phrase is intended to be limiting to the claim since all hybridization conditions have some level of stringency, be it high stringency, low stringency or some other degree of stringency.

Claims 42-51 are indefinite over the recitation "or a complementary nucleic acid of SEQ ID NO: 1" in independent claim 42 because it is not clear if applicant is claiming the sequence that is fully complementary to SEQ ID NO: 1 over its entire length or over some portion of SEQ

ID NO: 1. Furthermore, it is not clear if the claim intends to be draw to (a) an isolated DNA or RNA comprising at least 50 consecutive nucleotides of SEQ ID NO: 1 or an isolated DNA or RNA comprising a complementary nucleic acid of SEQ ID NO: 1 or (b) an isolated DNA or RNA comprising at least 50 consecutive nucleotides of SEQ ID NO: 1 or an isolated DNA or RNA comprising at least 50 consecutive nucleotides of a nucleic acid complementary nucleic acid to SEQ ID NO: 1.

Claim 52 is indefinite over the recitation "any of the nucleic acids of table 5" because it is not clear if this includes any nucleic acid whose actual sequence is recited in table 5 (i.e. SEQ ID NO: 46, 48, and 50) or if it also includes nucleic acids that are referred to by sequence identifier but whose actual sequences are not recited (i.e. SEQ ID NO: 47, 49, and 51).

Claim 53 is indefinite over the recitation "nucleic acid molecule of SEQ ID NO: 1" because it is not clear what it means for a nucleic acid molecule to be "of" the sequence. That is, it is not clear how much or how little of SEQ ID NO: 1 is required in order for the limitations of this claim to be met. Furthermore, it is not clear what it means for a nucleic acid to "contain" a polymorphism. It would be clearer if applicant required the presence of a polymorphic site as a particular position in a sequence.

Claims 54-55 are indefinite over the recitation "BAC RP11-0702C13 of SEQ ID NO: 1" because it is not clear from the claim how the BAC relates to SEQ ID NO: 1. That is, it is not clear if the BAC is SEQ ID NO: 1, so the claim requires, for example, 15 consecutive nucleotide bases from SEQ ID NO: 1, or if SEQ ID NO: 1 and the BAC are two different molecules.

Claims 56-63 are indefinite over the recitation "a complementary nucleic acid sequence of SEQ ID NO: 2" in independent claim 56 because it is not clear if applicant is claiming the

sequence that is complementary to SEQ ID NO: 2 over its entire length or over some portion of SEQ ID NO: 2. Recitation of "the complement of SEQ ID NO: 2" would obviate this rejection.

Claims 56-63 are indefinite over the recitation "under stringent conditions" because it is not clear how this phrase is intended to be limiting to the claim since all hybridization conditions have some level of stringency, be it high stringency, low stringency or some other degree of stringency.

Claims 64-73 are indefinite over the recitation "or a complementary nucleic acid of SEQ ID NO: 2" in independent claim 64 because it is not clear if applicant is claiming the sequence that is fully complementary to SEQ ID NO: 2 over its entire length or over some portion of SEQ ID NO: 2. Furthermore, it is not clear if the claim intends to be draw to (a) an isolated DNA or RNA comprising at least 50 consecutive nucleotides of SEQ ID NO: 2 or an isolated DNA or RNA comprising a complementary nucleic acid of SEQ ID NO: 2 or (b) an isolated DNA or RNA comprising at least 50 consecutive nucleotides of SEQ ID NO: 2 or an isolated DNA or RNA comprising at least 50 consecutive nucleotides of a nucleic acid complementary nucleic acid to SEQ ID NO: 2.

Claims 72 and 73 are indefinite over the recitation "A host cell according to claim 68" and "A host cell according to claim 69" because claims 68 and 69 do not recite host cells, the recite expression vectors. Thus, the phrase "A host cell" lacks proper antecedent basis in the claims.

Claim 74 is indefinite over the recitation "An isolated variant of SEQ ID NO: 2" because it is not clear how much or how little of SEQ ID NO: 2 is required in order for the limitations of this claim to be met. For example, is an oligonucleotide such as SEQ ID NO: 51 a "variant" of

SEQ ID NO: 2? Furthermore, it is not clear what it means for a nucleic acid to "contain" a polymorphism. It would be clearer if applicant required the presence of a polymorphic site as a particular position in a sequence. Furthermore, it appears that only one of the SNP sites referred to in table 5 (SEQ ID NO: 48/SEQ ID NO: 49) is within SEQ ID NO: 2, yet this claim implies that all three of the sites are contained within SEQ ID NO: 2. Clarification is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claims 34-38, 41-51, 52-55, 56-60, and 63-74 are rejected under 35 U.S.C. 102(b) as being anticipated by Shankar *et al.* (Biochem. Journal (1994) 300: 295-298).

Shankar *et al.* teach an isolated nucleic acid molecule comprising at least 50 nucleotides which hybridize under stringent conditions to SEQ ID NO: 1. Shankar *et al.* teach a cDNA

encoding a novel human airway mucin (p. 296) and disclose that this sequence is provided in the GenBank under the accession number U04799 (p. 295).

The nucleic acid taught by Shankar *et al.* has approximately 96% local similarity with nucleotides 1482-2630 of instant SEQ ID NO: 1. For applicant's convenience the alignment of this portion of SEQ ID NO: 1 with the sequence taught by Shankar *et al.* is attached to the Shankar *et al.* paper. Thus, the nucleic acid taught by Shanker *et al.* would be expected to hybridize with instant SEQ ID NO: 1 under high stringency conditions (limitation of claim 34(c)). The nucleic acid taught by Shankar *et al.* further comprises at least 50 consecutive nucleic acids of SEQ ID NO: 1. Nucleotides 2050-2504 of instant SEQ ID NO: 1 are identical to nucleotides 566-1019 of the sequence taught by Shankar *et al.* (alignment attached to reference). This rejection applies to claim 53 insofar as it is unclear how a nucleic acid can "contain" a SNP.

The nucleic acid taught by Shankar *et al.* has approximately 88% local similarity with nucleotides 2-1533 of instant SEQ ID NO: 2. For applicant's convenience the alignment of this portion of SEQ ID NO: 2 with the sequence taught by Shankar *et al.* is attached to the Shankar *et al.* paper. Thus, the nucleic acid taught by Shanker *et al.* would be expected to hybridize with instant SEQ ID NO: 2 under high stringency conditions (limitation of claim 56(d)). Nucleotides 570–1024 of instant SEQ ID NO: 2 are identical to nucleotides 566–1019 of the sequence taught by Shankar *et al.* (alignment attached to reference).

Shankar *et al.* teach that this nucleic acid was isolated from a cDNA library made with the Uni-Zap vector, and that positive plaques were obtained and purified (p. 296). Thus, Shankar *et al.* also teach expression vectors and host cells comprising this sequence.

Shankar *et al.* provide a polynucleotide comprising at least 15 consecutive nucleotides of any of SEQ ID NO: 49, wherein the 15 consecutive nucleotides include a SNP site selected from table 5. Nucleotides 13-39 of instant SEQ ID NO: 49 are identical to nucleotides 1373-1399 of the sequence taught by Shankar *et al.* This sequence is considered to be a nucleic acid molecule "of SEQ ID NO: 1" because it comes from within SEQ ID NO: 1. This sequences comprises at least 15 consecutive nucleotide bases of BAC RP11-0702C13 of SEQ ID NO: 1. Furthermore, this sequence is an isolated variant of SEQ ID NO: 2 wherein the variation contains at least one single nucleotide polymorphism of Table 5. The sequence taught by Shankar *et al.* is considered a "variant" of SEQ ID NO: 2 because it is substantially similar in structure to a fragment of the gene (see specification of the instant application, page 17, lines13-14 for definition of "variant.").

9. Claims 34-37, 42-47, 52-55, 56- 59, 64-69, and 74 are rejected under 35 U.S.C. 102(b) as being anticipated by the public use or sale of the BACPAC RPCI 11 filters.

Each filter is composed of isolated spots, wherein each spot is a particular BACPAC clone, thus, each clone is isolated. The BACPAC clones are inherently nucleic acids contained in expression vectors. These filters have been available for public use since at least August 1, 1997, as per an e-mail from Peter deJong of BACPAC Resources (see e-mail attached to BACPAC web page). The instant specification teaches that the RCPI-11 BAC library was the source of the nucleic acids of the instant invention (p. 30, lines 29-31). Thus, the filters provided by BACPAC resources comprise an isolated nucleic acid that would hybridize under stringent conditions to SEQ ID NO: 1. Further, these nucleic acids would comprise at least 50 consecutive

nucleotides of SEQ ID NO: 1. Thus, the filters provided by BACPAC resources comprise an isolated nucleic acid that would hybridize under stringent conditions to SEQ ID NO: 2. Further, these nucleic acids would comprise at least 50 consecutive nucleotides of SEQ ID NO: 2. The isolated nucleic acid provided for use or sale by BACPAC also inherently contains the three polymorphic sites listed in table 5. It also comprises a nucleic acid that encodes SEQ ID NO: 3.

10. Claims 52, 53, and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by GenBank record AA463832 (10-June-1997).

The GenBank record AA463832 provides a polynucleotide comprising at least 15 consecutive nucleotides of any of SEQ ID NO: 46, wherein the 15 consecutive nucleotides include a SNP site selected from table 5. Nucleotides 11-36 of instant SEQ ID NO: 46 are identical to the complement of nucleotides 51-76 of the sequence taught in the GenBank record. This sequence is considered to be a nucleic acid molecule "of SEQ ID NO: 1" because it comes from within SEQ ID NO: 1. This sequences comprises at least 15 consecutive nucleotide bases of BAC RP11-0702C13 of SEQ ID NO: 1.

11. Claims 52, 53, and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by GenBank record AC000367 (28-Aug-1997).

The GenBank record AC000367 provides a polynucleotide comprising at least 15 consecutive nucleotides of any of SEQ ID NO: 47, wherein the 15 consecutive nucleotides include a SNP site selected from table 5. Nucleotides 3-22 of instant SEQ ID NO: 47 are identical to nucleotides 32851-32870 of the sequence taught in the GenBank record. This sequence is considered to be a nucleic acid molecule "of SEQ ID NO: 1" because it comes from

within SEQ ID NO: 1. This sequences comprises at least 15 consecutive nucleotide bases of BAC RP11-0702C13 of SEQ ID NO: 1.

12. Claims 52, 53, 54, and 74 are rejected under 35 U.S.C. 102(e) as being anticipated by Tikoo *et al.* (US 6319716).

Tikoo *et al.* provide a polynucleotide comprising at least 15 consecutive nucleotides of any of SEQ ID NO: 48, wherein the 15 consecutive nucleotides include a SNP site selected from table 5. Nucleotides 7-21 of instant SEQ ID NO: 48 are identical to nucleotides 13657-13671 of SEQ ID NO: 35 taught by Tikoo *et al.* This sequence is considered to be a nucleic acid molecule "of SEQ ID NO: 1" because it comes from within SEQ ID NO: 1. This sequences comprises at least 15 consecutive nucleotide bases of BAC RP11-0702C13 of SEQ ID NO: 1. Furthermore, this sequence is an isolated variant of SEQ ID NO: 2 wherein the variation contains at least one single nucleotide polymorphism of Table 5. SEQ ID NO: 48 is considered a "variant" of SEQ ID NO: 2 because it is substantially similar in structure to a fragment of the gene (see specification of the instant application, page 17, lines13-14 for definition of "variant.").

13. Claims 52, 53, and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by WO8502610 (20 June 1985).

WO8502610 provides a polynucleotide comprising at least 15 consecutive nucleotides of any of SEQ ID NO: 50, wherein the 15 consecutive nucleotides include a SNP site selected from table 5. Nucleotides 14 to 28 of instant SEQ ID NO: 50 are identical to nucleotides 248-262 of the sequence beginning on p. 43. This sequence is considered to be a nucleic acid molecule "of SEQ ID NO: 1" because it comes from within SEQ ID NO: 1. This sequences comprises at least 15 consecutive nucleotide bases of BAC RP11-0702C13 of SEQ ID NO: 1.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 39, 40, 61, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shankar *et al.* in view of Lasky *et al.* (US 5304640).

Shankar *et al.* teach an isolated nucleic acid molecule comprising at least 50 nucleotides which hybridize under stringent conditions to SEQ ID NO: 1. Shankar *et al.* teach a cDNA encoding a novel human airway mucin (p. 296) and disclose that this sequence is provided in the GenBank under the accession number U04799 (p. 295).

The nucleic acid taught by Shankar *et al.* has approximately 96% local similarity with nucleotides 1482-2630 of instant SEQ ID NO: 1. For applicant's convenience the alignment of this portion of SEQ ID NO: 1 with the sequence taught by Shankar *et al.* is attached to the

Shankar *et al.* paper. Thus, the nucleic acid taught by Shanker *et al.* would be expected to hybridize with instant SEQ ID NO: 1 under high stringency conditions (limitation of claim 34(c)). The nucleic acid taught by Shankar *et al.* further comprises at least 50 consecutive nucleic acids of SEQ ID NO: 1. Nucleotides 2050-2504 of instant SEQ ID NO: 1 are identical to nucleotides 566-1019 of the sequence taught by Shankar *et al.* (alignment attached to reference). This rejection applies to claim 53 insofar as it is unclear how a nucleic acid can "contain" a SNP.

The nucleic acid taught by Shankar *et al.* has approximately 88% local similarity with nucleotides 2-1533 of instant SEQ ID NO: 2. For applicant's convenience the alignment of this portion of SEQ ID NO: 2 with the sequence taught by Shankar *et al.* is attached to the Shankar *et al.* paper. Thus, the nucleic acid taught by Shanker *et al.* would be expected to hybridize with instant SEQ ID NO: 2 under high stringency conditions (limitation of claim 56(d)). Nucleotides 570–1024 of instant SEQ ID NO: 2 are identical to nucleotides 566–1019 of the sequence taught by Shankar *et al.* (alignment attached to reference).

Shankar *et al.* teach that this nucleic acid was isolated from a cDNA library made with the Uni-Zap vector, and that positive plaques were obtained and purified (p. 296). Thus, Shankar *et al.* also teach expression vectors and host cells comprising this sequence.

Shankar *et al.* do not teach human host cells.

However, at the time the invention was made, the transformation of human host cells with vectors comprising nucleic acids encoding human proteins was routine in the art. Lasky *et al.* teach "Typical eukaryotic host cells are mammalian, such as Chinese hamster ovary cells or human embryonic kidney 293 cells (Col. 11, lines 36-38)." Therefore, It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have

transformed human host cells with vectors comprising the nucleic acid taught by Shankar *et al.* The ordinary practitioner would have been motivated to create such host cells for the benefit of expression the polypeptide encoded by the nucleic acid taught by Shankar *et al.* in order to characterize and study the polypeptide.

Conclusion

17. No claims are allowed.

18. Claims drawn to an isolated nucleic acid consisting of SEQ ID NO: 1 or the complement of SEQ ID NO: 1 would be allowable. Claims drawn to an isolated nucleic acid consisting of SEQ ID NO: 2 or the complement of SEQ ID NO: 2 would be allowable.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

JEFFREY FREDMAN
PRIMARY EXAMINER

Juliet C. Einsmann
Examiner
Art Unit 1634

June 14, 2002